DSJ1&2-PR Exh 528

Message

From: Harper, Karen [Harper, Karen]
Sent: 2/29/2008 4:19:05 PM
To: Ratliff, Bill
Subject: FW: DEA Suspicious Order Monitoring Update

Karen Harper
Manager, DEA Compliance
Covidien
Mallinckrodt Pharmaceuticals
3600 North Second Street
St. Louis, MO 63147

office phone (314) 654-1868
24/7 access [redacted]

From: Harper, Karen
Sent: January 08, 2008 3:53 PM
To: France, Kimberly P
Subject: FW: DEA Suspicious Order Monitoring Update

Karen Harper
Manager, DEA Compliance
Covidien
Mallinckrodt Pharmaceuticals
3600 North Second Street
St. Louis, MO 63147

office phone (314) 654-1868
24/7 access [redacted]

From: Harper, Karen
Sent: January 04, 2008 2:52 PM
To: Pheney, Michael
Cc: Kaiman, Vince J; Levy, JoAnne; Ratliff, Bill; Rausch, Jim H
Subject: DEA Suspicious Order Monitoring Update

The attached memo was received today and targets DEA registered Manufacturers as well as Distributors in terms of Suspicious Order Monitoring obligations.
72 FR 36487 (2007) referenced in the DEA memo is also attached.

This memo differs from a similar memo DEA sent to Distributors (only) in 2006 which is also included.

Redacted - A/C Privilege

Karen Harper
Manager, DEA Compliance

Covidien
Mallinckrodt Pharmaceuticals
3600 North Second Street
St. Louis, MO 63147

office phone (314) 654-1868
24/7 access [redacted]

From: mailmkg@tycohealthcare.com [mailto:mailmkg@tycohealthcare.com]
Sent: January 04, 2008 2:43 PM
To: Harper, Karen
Subject: Attached Image

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

MALLINCKRODT INC
3600 NORTH SECOND STREET
ST LOUIS MO, 63147-0000

December 27, 2007

In reference to registration
PM0037451

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control